

EXHIBIT N

1 (Marked Wilson Exhibit Nos. 1 - 7.)

2 ANNE HOLLAND WILSON,

3 having been first duly sworn, testified as follows:

4 E X A M I N A T I O N

5 BY MR. DAVIS:

6 Q. Good morning, Ms. Wilson. Would you state

7 your full name for the record, please?

8 A. Anne Holland Wilson.

9 Q. Ms. Wilson, we've met. I'm Paul Davis. I'll
10 be asking you some questions today. We'll get started.

11 I've handed you some premarked exhibits,
12 1 through 7. Could you take a look at those? I think
13 the first one is the notice of deposition. Are you
14 familiar with it?

15 A. I've browsed it.

16 Q. And we've requested some documents just to
17 bring with you. Can you just give us an overview of
18 what, if anything, you brought with you today?

19 A. I believe there's a copy of each of my
20 reports --

21 Q. Okay. Anything --

22 A. -- that are clean copies. They're in the
23 binder there.

24 (Marked Wilson Exhibit Nos. 8 - 10.)

1 THE WITNESS: Right there, yeah. Thank
2 you. I knew it was in here somewhere.

3 A. So they didn't look at the technique, the
4 surgical technique, and how it was fixated. They didn't
5 look at how it was implanted. I mentioned those,
6 through the obturator membrane. They didn't look how
7 the change to the mesh ends and how that would work with
8 the helical passers and the winged guide and how that
9 would work, to the needles connected on the delivery
10 system. So --

11 Q. (BY MR. DAVIS) Okay. Will you agree that the
12 2007 version of ISO 14971 includes a discussion of some
13 examples of risk analysis techniques?

14 A. In the annex?

15 O. Yes.

16 A. Yes.

17 Q. And could you turn to that? Do you see
18 Annex G?

19 MR. WALLACE: And after this, we're going
20 to take a break.

21 MR. DAVIS: Sure.

22 Q. (BY MR. DAVIS) Do you see -- well, first of
23 all, is there any provision anywhere in ISO 14971 that
24 requires the use of an FMEA to do a risk analysis? Is

1 that anywhere in the ISO?

2 A. No.

3 Q. Okay. Is it in any standard that applies to
4 Ethicon? Any industry standard, I'm talking about. Is
5 there any industry standard that requires the FMEA
6 approach to risk analysis?

7 MR. WALLACE: Objection to form.

8 A. That tool is not a requirement.

9 Q. (BY MR. DAVIS) Okay. Now -- and do you see
10 where, in Annex G of Exhibit 12, they do give a general
11 description of what an FMEA is, correct?

12 A. Yes. And Ethicon has chosen the FMEA to be
13 their tool to do risk analysis. It's in their
14 procedures.

15 Q. They chose that at certain times, correct?

16 A. They've chosen that -- it was throughout the
17 life of these products.

18 Q. Okay. Throughout the life of TVTR?

19 A. In each of these cases, it talks about the
20 procedures.

21 Q. Okay.

22 A. And that was the only tool of these that were
23 used.

24 Q. Okay. And would you agree that an FMEA is a

Anne Holland Wilson

1 COUNTY OF HARRIS)

2 STATE OF TEXAS)

3

4 REPORTER'S CERTIFICATE

5

6 I, KERRIENNE L. BOND, Certified Shorthand Reporter
7 in and for the State of Texas, hereby certify that this
8 transcript is a true record of the testimony given by
9 the witness named herein, after said witness was duly
10 sworn by me.

11 I further certify that I am neither attorney nor
12 counsel for, related to, nor employed by any of the
13 parties to the action in which this testimony was taken.
14 Further, I am not a relative or employee of any attorney
15 of record in this cause, nor do I have a financial
16 interest in the action.

17 Certified to by me this 24th day of March 2016.

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21 KERRIENNE L. BOND, CSR No. 8537

Expiration Date: 12-31-16

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